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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,766

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Jacob Korevaar

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EXAMINER

STUART, COLIN W

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/590,766	<b>Applicant(s)</b> KOREVAAR ET AL.	
	<b>Examiner</b> COLIN STUART	<b>Art Unit</b> 3771	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 25-27 is/are rejected.
- 7) ☒ Claim(s) 5-24 and 28-35 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 August 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/1/10</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Specification***

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Note that the language "comprising" and "means" is improper language format for an abstract.

### ***Priority***

2. Acknowledgment is made of applicant's claim for foreign priority based on applications filed in the Netherlands on 2/24/04 and 5/10/04. It is noted, however, that applicant has not filed a certified copy of the 1025556 and 1026154 applications as required by 35 U.S.C. 119(b).

### ***Drawings***

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the control means

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must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

4. Claims 5-24 and 28-35 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend on another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 5-24 and 28-35 not been further treated on the merits.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claim 1, it appears the applicant is trying to invoke 25 U.S.C. 112 sixth paragraph in using the 'means for' followed by functional language; however, the specification lacks disclosure of the structure(s) which are the control means for and the supply means for rendering the limitations indefinite.

In regards to claim 3, the language "a catalytic burner, such as a fuel cell" is indefinite as the examiner cannot ascertain the limitation intended by this language.

In regards to claims 25 and 26, the claimed method steps are unclear as there is not any structure recited which is used for performing the claimed method steps which are therefore unclear.

Claims 2, 4 and 27 are rejected based upon dependency to a rejected claim.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

**7. Claims 1-4, 25, and 27 are rejected under 35 U.S.C. 102(a) as being anticipated by Esser (WO 03/094640), based on the English language equivalent Publication (2005/0211243).**

In regards to claim 1, Esser shows a device for administration of a substance to a mammal by means of inhalation which includes aerosol means (7 & 8; see para. 0031) for creating an aerosol, control means (see para. 0034; the feature of providing adjustable air supply and temperature/humidity regulation controls the size of the vapor particles produced by aerosol means) for manipulating the aerosol in order to thereby control the particle size of the aerosol, wherein the device is provided with supply means (15; see para. 0028) for adding a substance to the aerosol, prior to or upon release of the aerosol from the device (see para. 0031; note that the vapor/aerosol produced by the fuel cell 7 and 8 is then mixed with inhalation additives).

In regards to claim 2, the Esser device's aerosol means includes a mist generator. Note that the aerosol means 7 & 8 generates water vapor, a mist.

In regards to claim 3, the Esser device's aerosol means includes a catalytic burner, such as a fuel cell (see para. 0006 and 0010).

In regards to claim 4, the Esser device includes an aerosol Chamber for creating the aerosol in the chamber (note that the housing and other elements which surround the fuel cell 7 & 8 define the chamber which the vapor/aerosol is produced).

In regards to claim 25, through the use of the Esser device as described above in the rejection of claim 1, the method steps of: creating an aerosol (see para. 0031 In. 1-6), manipulating the aerosol by adding or removing energy from the aerosol in order to control particle size (see para. 0034), administering the aerosol to the mammal (see para. 0031 In. 12-15), and adding a substance to the aerosol prior to administration (see para. 0031 In. 6-12) are performed.

In regards to claim 27, through the use of the Esser device the step of adding a substance to the aerosol is executed after the completion of creating and manipulating the aerosol (see para. 0031 and 0034).

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**9. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Esser (WO 03/094640), based on the English language equivalent Publication (2005/0211243).**

In regards to claim 26, the Esser device and method of use as discussed above, teaches all the limitations but is silent as to explicitly identifying a target area in the respiratory tract/lungs of the user and calculating a preferred state and condition for the aerosol. However, the production of the Esser device includes determining an area in the user's respiratory tract/lungs for a substance to be administered (the Esser device is designed and uses the method step of identifying a target area for the additives to reach the user for effect, in this case nicotine additive for example) and the device is designed such that the a preferred state and condition for the aerosol is calculated and produced such that the device functions for its intended purpose of delivering an inhalation additive to the user for effect. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method step of identifying a preferred target area in the respiratory tract of the patient and calculating a preferred state/condition for the aerosol in order to optimize the effects of the drug delivery.



### ***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following documents are considered to be pertinent art: Esser (DE 10055838) and Rabin et al. (2006/0196968) are both related to fuel cells utilized to produce inhalable vapor and Liu et al. (2003/0143444) is related to a fuel cell in particular.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLIN STUART whose telephone number is (571)270-7490. The examiner can normally be reached on M-F 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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